

7-5/2013/EU/WC-0067
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated

07 JUN 2022

To

**M/s Dr. Reddy's Laboratories Limited,
Chemical Technical Operations Unit-VI,
APIIC Industrial Estate, Pydibhimavaram Village, Ranasthalam Mandal,
Srikakulam District -532 409, Andhra Pradesh, India**

SUB:- Written Confirmation of M/s Dr. Reddy's Laboratories Limited, Chemical Technical Operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram Village, Ranasthalam Mandal, Srikakulam District -532 409, Andhra Pradesh, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your applications No. WC/RE/2021/1060, 1077 & 1167 submitted to CDSCO, Hyderabad Zone office, and the recommendation received from DDC (I), Hyderabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).
2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.
3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.
4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.
5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.
7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.
8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue,	Valid Upto
01	05	7 JUN 2022	07.07.2025
02	13	7 JUN 2022	07.07.2025

Yours faithfully,



(Dr. V. G. Somani)
Drugs Controller General (India)

2/6
07-06-22



Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Dr. Reddy's Laboratories Limited,
Chemical Technical Operations Unit-VI, APIIC
Industrial Estate, Pydibhimavaram Village,
Ranasthalam Mandal, Srikakulam District -532 409,
Andhra Pradesh, India**

2. Manufacturer's license number: **165/SK/AP/1995/B/R**

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of APIs:

As per list Annexed

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7):

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 05.05.2022 & 06.05.2022.

The Written Confirmation remains valid until: 07.07.2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India.

Name and function of responsible person: Dr. V. G. Somani.
Drugs Controller General (India).

E-mail:

Telephone no.:

Fax no.:

dci@nic.in,

+91-11-23236965

+91-11-23236973

Signature

V. G. Somani
07-06-2022

07 JUN 2022

Stamp of the authority and date





Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Dr. Reddy's Laboratories Limited,
Chemical Technical Operations Unit-VI, APIIC
Industrial Estate, Pydibhimavaram Village,
Ranastharam Mandal, Srikakulam District -532 409,
Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Glatiramer Acetate IH	Manufacturing & Packing
2.	Decitabine IH	Manufacturing & Packing
3.	Eslicarbazepine Acetate IH	Manufacturing & Packing
4.	Esomeprazole Magnesium USP	Manufacturing & Packing
5.	Nilotinib Hydrochloride IH	Manufacturing & Packing

ITEM(S) FIVE (05) ONLY

The Written Confirmation remains valid until: 07.07.2025

o/c

Signature 
07-06-22

Stamp of the authority and date



07 JUN 2022



Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Dr. Reddy's Laboratories Limited,
Chemical Technical Operations Unit-VI, APIC
Industrial Estate, Pydibhimavaram Village,
Ranasthalam Mandal, Srikakulam District -532 409,
Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Sugammadex Sodium IH	Manufacturing & Packing
2.	Mirabegron Amorphous IH	Manufacturing & Packing
3.	Sitagliptin Hydrochloride Monohydrate IH	Manufacturing & Packing
4.	Agomelatin Phosphoric Acid IH	Manufacturing & Packing
5.	Fingolimod Hydrochloride IH	Manufacturing & Packing
6.	Ibandronate Sodium Monohydrate IH	Manufacturing & Packing
7.	Ibandronate Sodium Form Beta IH	Manufacturing & Packing
8.	Lurasidone Hydrochloride IH	Manufacturing & Packing
9.	Mirabegron IH	Manufacturing & Packing
10.	Nizatidine USP/Ph. Eur	Manufacturing & Packing
11.	Prasugrel Base IH	Manufacturing & Packing
12.	Enzalutamide IH	Manufacturing & Packing
13.	Pomalidomide IH	Manufacturing & Packing

ITEM(S) THIRTEEN (13) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 07.07.2025

Signature

Handwritten signature
07-06-2022

07 JUN 2022

Stamp of the authority and date

